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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,257	04/09/2001	Michael Buchanan	P66570US0	3204

7590

06/30/2005

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EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/833,257	Applicant(s) BUCHANAN ET AL.	
	Examiner Brian S. Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10 and 13-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Handwritten initials/signature

DETAILED ACTION

Summary of Action

1. The objection of the claims 12-14 and 20 is not maintained in light of the amendment.
2. The rejection of the claims 17-20 under 35 USC 112, first paragraph, as failing to comply with written description requirement, is not maintained in light of the amendment. However, the rejection of the claim 15 under the 35 USC 112, first paragraph, is maintained for the reasons of record.
3. The rejection of the claims the claims 12 and 14-23 under 35 USC 112, first paragraph, as failing to comply with scope of enablement requirement, is not maintained in light of the amendment.
4. The rejection of the claims 10 and 20 under 35 USC 112, second paragraph, is not maintained in light of the amendment.
5. The rejection of the claims 14-23 and 26 under 35 USC 103(a) as being unpatentable over Vanderhoek (US 60777525) in view of Breivik et al. (US 5502077) is maintained for the reasons of record.
6. Applicant's amendment (changing the scope of the claim invention) necessitates a new ground of the rejection in this Office Action.

Status of Application

7. By Amendment filed December 03, 2004, claims 11-12 and 26 have been cancelled and claims 10, 13-15 and 20 have been amended. Claims 10, 13-23 are currently pending for prosecution on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 15 is rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The present claim is drawn to a composition comprising 13-hydroxyoctadeca-9Z, 11E-dienoic acid (13-HODE) in its free form and at least one carrier.

The instant specification discloses a composition comprising 13-HODE either in its free form or with a pharmaceutically acceptable carrier, auxiliary or excipient, wherein the carrier, auxiliary or excipient may be mono-, di- or triglyceride oil, corn, sunflower, safflower, cottonseed, grape seed, olive, evening primrose, borage, fish body and fish liver oils, or an ester of a fatty acid containing 16-26 carbon atoms and one or more double bonds; wherein the ester may be ethyl-eicosapentaenoic (ethyl-EPA), oleic, linoleic, alpha-linoleic, stearidonic, gamma-linolenic, dihomogammalinolenic, arachidonic, docosapentaenoic or docosahexaenoic (DHA) (page 16, lines 4-12). The specification also discloses that said composition may include emulsifying agents, antioxidants (e.g., ascorbyl palmitate, tocopherols and ascorbic acid), buffering agents, preservatives, humectants, penetration enhancers, chelating agents, gelforming agents, ointment bases, perfumes and skin protective agents (page 21, lines 2-136). The specification is based on applicant's alleged discovery of finding of "stable" composition by

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incorporating 13-HODE into a triglyceride oil carrier or an ester of a fatty acid containing 16-26 carbon atoms and one or more double bonds (page 25, lines 3-4; page 26, lines 20-23), particularly EPA and DHA, more particularly ethyl ester of EPA (page 25, lines 10-14; page 26, line 23 thru page 27, line 2).

As preferred embodiment of the invention, the pharmaceutical composition of 13-HODE in combination with carrier selected from the group consisting of corn, sunflower, safflower, cottonseed, grape seed, olive, evening primrose, borage, fish body, fish liver oils, ethyl-eicosapentaenoic (ethyl-EPA), oleic, linoleic, alpha-linoleic, stearidonic, gamma-linolenic, dihomogammalinolenic, arachidonic, docosapentaenoic and docosahexaenoic (DHA), specifically a combination product containing 13-HODE in combination with corn oil or an ethyl ester of a 16-26 carbon fatty acid with one or more double bonds, such as ethyl-oleate, ethyl-linolate, ethyl-EPA or ethyl-DHA (page 22, lines 1-18). As another preferred embodiment of the invention, the pharmaceutical combination containing 13-HODE and omega-3 fatty acids, like EPA, DHA, derivatives of EPA and DHA, ethyl-EPA and ethyl-DHA is disclosed (page 22, lines 22-24).

As discussed above, the specification provides sufficient written description for the composition comprising (A) 13-HODE and (B) omega-3 fatty acids selected from the group consisting of EPA, DHA, ethyl-EPA and ethyl-DHA, or the composition comprising (A) 13-HODE and (C) carrier selected from the group consisting of a mono-, di- or triglyceride oil; corn, sunflower, safflower, cottonseed, grape seed, olive, evening primrose, borage, fish body, fish liver oils; an ester of a fatty acid containing 16-26 carbon atoms and one or more double bonds (e.g., oleic, linoleic, alpha-linoleic, stearidonic, gamma-linolenic, dihomogammalinolenic,

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arachidonic and docosapentaenoic). The specification clearly does not provide an adequate representation regarding the composition comprising (A) 13-HODE, (B) omega-3 fatty acid selected from the group consisting of EPA, DHA, a derivative of EPA and a derivative of DHA and (C) carrier selected from the group consisting of a mono-, di- or triglyceride oil; corn, sunflower, safflower, cottonseed, grape seed, olive, evening primrose, borage, fish body, fish liver oils; and an ester of a fatty acid containing 16-26 carbon atoms and one or more double bonds (e.g., oleic, linoleic, alpha-linoleic, stearidonic, gamma-linolenic, dihomogammalinolenic, arachidonic and docosapentaenoic, made by the presently claimed invention. In other words, the specification provides insufficient written description to support the instantly required (A)/(B)/(C) combination. None of the claimed compositions in claims 15-20 meets the written description provision of 35 USC 112, first paragraph.

Vas-Cath Inc. Mahurkar, 19 USPQ2d 1111, makes clear the “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116).

With the exception of the above mentioned (A) and (B) combination or (A) and (C) combination, the skilled artisan cannot envision (A)/ (B)/(C) or (B)/(C) combination.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

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...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966(1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”) Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Streber (US 5102912)

Streber expressly teaches a oral composition comprising hydroxyoctadecadienic acid (i.e., 13-hydroxy-9(cis)-11(trans)-octadecadienic acid (13-HODE)) and carrier (i.e., soya oil), wherein said compound is administered in administered daily dose of from about 100 to 100mg;

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and wherein said composition is prepared in various dosage forms including tablet, capsule and dragees. See column 3, lines 3-65 and claims 1, 9, 15-16 and 19.

Although 13-hydroxy-9(cis)-11(trans)-octadecadienic acid (13-HODE) is not specifically disclosed as the embodiment with soya oil or triglyceride, however, one of ordinary skill in the art would have been able to select 13-HODE from the limited number of compounds (four compounds disclosed in column 3, lines 44-47) listed as the preferred pharmaceutical preparation in tablet form, and "at once envisage" the subject matter within claims 15-17 of the instant invention. Thus, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 14-17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderhoek (US 60777525) in view of Breivik et al. (US 5502077).

Vanderhoek teaches the use of conjugated linoleic acids (CLAs) such as 13-HODE for inhibiting platelet aggregation (column 1, lines 3-7; column 2, lines 20-28; column 3, lines 25-36 and 55) or reducing LDL-cholesterol level (column 1, lines 42-49).

Breivik teaches the use of fatty acid composition comprising omega-3-fatty acids such as EPA, DHA and ethyl ester form of EPA or DHA, antioxidants (e.g., ascorbic acid, d-alpha tocopherol) and additives (e.g., colouring agents) for inhibiting platelet aggregation (Table 10; column 9, lines 65-66) or lowering LDL-cholesterol level (Table 8; column 9, lines 25-28; column 11, lines 14-38).

The teaching of Vanderhoek differs from the claimed invention in (i) the combination of 13-HODE, and omega-3 fatty acid (i.e., EPA, DHA, ethyl-EPA and ethyl-DHA); (ii) the specific dosage amount of 13-HODE; (iii) the specific dosage form; and optionally (iv) further comprising antioxidants (e.g., ascorbic acid, d-alpha tocopherol) and additives (e.g., colouring agents). To incorporate such teaching into the teaching of Vanderhoek, would have been obvious

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in view of Breivik teaches the use of fatty acid composition comprising omega-3-fatty acids such as EPA, DHA and ethyl ester form of EPA or DHA, antioxidants (e.g., ascorbic acid, d-alpha tocopherol) and additives (e.g., coloring agents) for inhibiting platelet aggregation or lowering LDL-cholesterol level.

The above references in combination make clear that the use of 13-HODE, omega-3 fatty acids such as EPA, DHA, ethyl-EPA and ethyl-DHA and antioxidants for inhibiting platelet aggregation or lowering LDL-cholesterol level are well known in the art. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component.

With respect to claims 15, 17 and 19-20, when said carrier is ethyl-eicosapentaenoic acid (EPA) or docosahexaenoic acid, the scope of the claimed composition in claims 15, 17 and 19-20 overlaps to the scope of claim 14 composition. Therefore, the reference in combination makes obvious the claimed composition.

With respect to the specific dosage of 13-HODE (claim 16) and the specific dosage forms (claim 21), those of ordinary skill in the art would have readily optimized effective dosages amounts or dosage forms as determined by good medical practice and the clinical condition of the individual patient. Determination of appropriate dosage amounts of each ingredients in said composition or dosage forms involving each of the above mentioned formulations would have been apparent to those of ordinary skill in the art, and routinely made by those of ordinary skill

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in the art and be within the ability of tasks routinely performed by them without undue experimentation.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

11. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Streber (US 5102912) in view of Carlsson et al. (WO 99/44585).

The teaching of Streber has been discussed in above 35 USC 102(b) rejection.

Carlsson is being supplied as a reference to demonstrate the use of evening primrose oil, soybean oil, borage and sunflower oil as suitable carrier for the 13-HODE (page 4, line 35 thru page 5, line 3).

The teaching of Streber differs from the claimed in the use of other mono, di, or triglyceride such as corn, sunflower, safflower, cottonseed, grape seed, olive, evening primrose, borage, fish body and fish liver oils. To incorporate such teaching into the teaching of Streber, would have been obvious in view of Carlsson who teaches the routine known in utilizing evening primrose oil, borage and sunflower oil as functional equivalent as soya (soybean) oil in preparing 13-HODE composition.

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The above references in combination make clear that use of triglycerides such as corn, sunflower, evening primrose, borage and soybean oil as secondary agent in preparing 13-HODE formulation is well known in the art. The above references in combination also make clear that the formulation of 13-HODE into topical form, tablet, capsule, dragees or solutions is old and well known in the art. Thus, it would have been obvious to make the claimed composition comprising 13-HODE and carrier (i.e., corn, sunflower, evening primrose and borage) since the examiner takes the art-recognized equivalent of corn, sunflower, evening primrose, borage and soybean oil as triglycerides for their use in preparing 13-HODE formulation and the selection of any of these known triglycerides to prepare 13-HODE formulation would be within the level of ordinary skill in the art.

Response to Arguments

12. Applicant's arguments filed December 03, 2004 have been fully considered but they are not persuasive.

In response to the Examiner's rejection of the claims 15 and 17-20 under 35 USC 112, first paragraph, as failing to comply with written description requirement, Applicant amended the claims, particularly claim 15 to recite "an oral pharmaceutical composition comprising 13-hydroxyoctadeca-9Z, 11E-dienoic acid (13-HODE) in its free form and at least one pharmaceutically acceptable carrier". According to the amended claim, the scope of the claimed composition encompasses a composition comprising 13-HODE dissolved in any combination of carriers selected from the group consisting of a mono-, di- or triglyceride oil; corn,

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sunflower, safflower, cottonseed, grape seed, olive, evening primrose, borage, fish body, fish liver oils; an ester of a fatty acid containing 16-26 carbon atoms and one or more double bonds (e.g., ethyl-eicosapentaenoic acid, oleic, linoleic, alpha-linoleic, stearidonic, gamma-linolenic, dihomogammalinolenic, arachidonic and docosapentaenoic). Since the interpretation of the instant claim allows for the inclusion of any other unspecified component even in major amounts in said composition, the claimed composition could contain (A) 13-HODE, (B) eicosapentaenoic acid (ethyl-EPA) and (C) the other carriers. As discussed above in the 35 USC 112, first paragraph, rejection, the specification clearly does not provide an adequate representation regarding the composition comprising (A) 13-HODE, (B) ethyl-EPA and (C) carrier selected from the group consisting of a mono-, di- or triglyceride oil; corn, sunflower, safflower, cottonseed, grape seed, olive, evening primrose, borage, fish body, fish liver oils; and an ester of a fatty acid containing 16-26 carbon atoms and one or more double bonds (e.g., oleic, linoleic, alpha-linoleic, stearidonic, gamma-linolenic, dihomogammalinolenic, arachidonic and docosapentaenoic, made by the presently claimed invention. Therefore, the Examiner maintains the rejection of the claim 15 under the 35 USC 112, 1st paragraph.

Applicant's argument in the response takes the position that the 9,11 octadecadienoic in Vanderhoek (Example 3) is a different compound from 13-HODE. Furthermore, Applicant alleges that Figure 3 of Vanderhoek teaches away from the use of 13-HODE as an inhibitor of platelet aggregating TXB2 formation.

This argument is not found persuasive. Unlike the Applicant's argument, Vanderhoek teaches the use of hydroxyl derivatives of the 9, 11, and/or 10,12-isomers including 13-HODE as

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the suitable agent having characteristic of “more potent as a thromboxane inhibitor than the parent 9,11-18:2” (column 3, lines 30-31) or “enhanced its inhibitory potency relative to the non-hydroxylated analog about five fold” (column 5, lines 40-41; Table 2) for the claimed invention (see column 3, lines 25-36 and 55). Although 13-HODE is not specifically disclosed as the embodiment with other ingredients including monoglyceride, however, one of ordinary skill in the art would have known that hydroxyl derivatives of 9,11 octadecadienoic such as 13-HODE would have similar activities as the exemplified the 9,11 octadecadienoic.

Applicants argument in the response takes the position that a person skilled in the art would realized that all prior art antithrombotic treatments, including those taught by Vanderhoek and Breivik, impact significantly on coagulation and/or platelet function and render platelets hemostatically dysfunctional; i.e., place the patient at risk of bleeding.

This argument is not found persuasive. Firstably, there is no indication in the instant claims that the claimed composition is able to “return the vessel wall to homeostatic conditions without rendering the patient hemostatically dysfunctional”. In other words, the interpretation of the instant claims do not require of the alleged advantage of “without rendering the patent hemostatically dysfunctional”. Therefore, the referenced teachings in combination make obvious the claimed invention. Finally, the state of art acknowledges the numerous possible combinations of antplatelet agents, antithrombic agents, anti-coagulant agents and fibrinolytic agents for the potential treatment of thrombosis (see for example US 6462021; US5945432; US 6245782, etc...). Unlike Applicant’s argument, one having ordinary skill in the art would have expected that combination of ingredients each of which is taught by prior art to be useful for inhibiting

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platelet aggregation would provide enhanced pharmacological activity by their additive effect of each individual component. Furthermore, one having ordinary skill in the art would have been motivated to combine the above references and make the modification to decrease the possible adverse effects by decreasing the amounts of each ingredients normally administered for the treatment of thrombosis. In absence evidence to the unexpected results or superior results of the claimed composition over the prior art, the Examiner maintains that the instant invention is obvious over the Vanderhoek (US 60777525) in view of Breivik et al. (US 5502077).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Claims 10 and 13 are allowed.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614



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